SUMMARY OF THE QUALITY SYSTEMS COMMITTEE MEETING MARCH 16, 1999

The Quality Systems (QS) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on March 16, 1999, at 11 a.m. Eastern Standard Time (EST). The meeting was led by its chair, Mr. Joe Slayton of the U.S. Environmental Protection Agency's (EPA) Region III. A list of action items is given in Attachment A. A list of participants is given in Attachment B. A list of parking lot issues and frequently asked questions (FAQs) is given in Attachment C. Attachment D presents the QS Committee approach to handling comments, comment acknowledgment form letter, commenter template, and guiding principles for reviewing comments and the standard. Changes to the language in Chapter 5 proposed at this teleconference are reflected in version 5.10.3 of the standard. *The purpose of the meeting was to review action items from previous meetings and to discuss comments received at the NELAC IVi meeting.*

REVIEW OF ACTION ITEMS FROM THE PREVIOUS MEETING

The committee reviewed and approved, with editorial changes, the new list of FAQs.

The committee discussed Chuck Glowacki's definition of the term *blank.* This language will be added to Sections 5.10.2.1 and C.1 to clarify the meaning of *blank matrix.*

The QS Committee reviewed Donivan Porterfield's and Raymond Frederici's introductory paragraphs for the new appendices that list the procedures and records/documentation requirements in Chapter 5. Language was added to each paragraph so that it is clear that these new appendices (Appendices F and G) are not requirements but are guidance that the reader may find helpful.

Regarding references, the comment was made that the references for Chapter 5 were intended to be only those documents that were used to generate the standard. The committee agreed not to include in Appendix A the additional references that were proposed for calibration and detection.

The committee has received comments from the Field Activities *ad hoc* committee. The Field Activities' approach for developing standards is to include requirements in the existing chapters whenever possible. Requirements unique to field measurements and testing will be put in a separate chapter. Mr. Slayton will send a letter to the Field Activities committee explaining that the QS Committee will wait until the Field Activities committee is established as a standing committee before addressing their comments. This committee will be established by NELAC vote and this vote will give an official recognition of support from NELAC for the extensive revisions to Chapter 5 that the submitted comments would require. In addition, comments were made that the QS Committee may not have the expertise to properly address field activities. It was decided that, at least in the near term, Chapter 5 should focus on laboratory quality systems as the Committee does not have time to address the field issues along with the current backlog of comments. A suggestion was made that the

Field Activities Committee could develop their own chapter, which at some point could be coordinated with Chapter 5.

With regards to more stringent requirements, the QS Committee reviewed language that was modified to be consistent with the idea that a mandated method should be followed where it is unclear which is more stringent, the requirements of Chapter 5 or those of a method.

DISCUSSION OF ISSUES RAISED AT NELAC IVI

Section 5.9.4.2.1.f: The language was modified to clarify the meaning of this requirement.

Section 5.9.4.2.1.d: The committee discussed the meaning of initial versus continuing calibration. It was agreed that an initial instrument calibration is used to quantitate results. Language was added to the introductory paragraph clarifying what is covered in Section 5.9.4.2.1, Initial Instrument Calibration, and Section 5.9.4.2.2, Continuing Instrument Calibration Verification.

Section 5.9.4.2.1.b: A requirement was added to document the name of the analyst(s) performing the initial instrument calibration.

Section 5.9.4.2.1.b,c,e: The language was revised so that the term *continuing calibration verification* is used consistently.

Section 5.9.4.2.1.h: Language was added specifying that laboratories do not have to include in the calibration standards concentrations at or below the regulatory limit/decision level if the laboratory demonstrates that this level is below their detection limit.

Section 5.9.4.2.1.i: This section was amended to require an absolute minimum of two calibration points.

Section 5.9.4.2.2.b: The language was modified allowing only one continuing calibration check (at the beginning of each analytical batch), if the analytical instrument uses internal standards.

Section 5.9.4.2.2.c: The language was modified to be consistent with the requirements in 5.9.4.2.2.b -- allowing them to run one continuing calibration check when the analytical instrument uses internal standards.

Attachment A

ACTION ITEMS
QUALITY SYSTEMS COMMITTEE
MARCH 16, 1999

Item No.	Action Item	Date to be Completed
1.	The QS Committee will revisit the issue of the *work cell* in 5.6.2	
2.	Mr. Glowacki to lead a discussion, at an upcoming teleconference, concerning the comments and revisions to the air testing section of Chapter 5.	
3.	QS Committee owes a response to comments received from Ms. Karopilak and Mr. Miller of the New Jersey Department of Environmental Protection. Also, comments received from Mr. Hall of Quanterra have been divided among the committee participants to prepare draft responses.	
4.	Mr. Slayton to send the latest version of the template that should be used when comments are sent to the QS Committee to Ms. Carolyn Cross for posting to the NELAC Web site.	
5.	Mr. Slayton will send the revised list of Frequently Asked Questions to Ms. Irene Ronnig. The up-to-date list is routinely attached to the minutes.	
6.	Mr. Slayton will send Mr. Glowacki's new definition of *blank* to the QS Committee participants.	
7.	Mr. Slayton to add Appendices F and G to Chapter 5 along with the introductory paragraphs for each appendix.	
8.	Mr. Slayton will respond to the comments received from Mr. Charley Dyer from New Hampshire.	
9.	Mr. Slayton will send a letter to the Field Activities Committee explaining the QS Committee approach to handling their comments.	
10.	The next teleconference is March 30th from 2:00 to 5:00 p.m. EST on 202-260-8330, access number 8983#.	

Attachment B

PARTICIPANTS
QUALITY SYSTEMS COMMITTEE
MARCH 16, 1999

Name	Affiliation	Phone/Fax/E-mail
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Attachment C

PARKING LOT ITEMS/ISSUES AND FREQUENTLY ASKED QUESTIONS
Quality Systems Committee
March 16, 1999

Items/issues will remain in the Parking Lot until they are completed.

1. Air Appendix

Need to review and finalize

2. Proposed New Appendix

Appendix for listing of required records and procedures. Need introduction and have it all pulled into one table. Need to reach consensus on the table and the suggested introduction provided by D. Porterfield and Ray Frederici (leads).

3. Initial Demonstration of Capability (IDOC):

Need to address an IDOC for tests for which you can not spike. Also, does IDOC need to be universal and address all medias? Donivan Porterfield is lead.

4. Definitions/Glossary

Changes necessary to be consistent with Program Policy and Structure proposal. QS Committee will review definitions/glossary at interim meeting.

5. Q & A are due to Outreach Committee.

6. Review comments from NELAC IVi.

7. Review comments received since NELAC IVi.

8. Need to vote in two new members to QS committee.

All candidates must be identified and voted upon by NELAC Committees by May 10, 1999. All appointments by the NELAC Chair must be complete by May 17, 1999.

9. Final QS Chapter for NELAC V

Final changes to standards are due to Research Triangle Institute by April 29, 1999 for posting on the NELAC Web page prior to the annual meeting. This version will be posted within a week and half of receipt and will remain as the final proposed text for Annual Meeting.

10. Agenda for NELAC V

Final committee agendas, including discussion items and times, are due to Elizabeth Dutrow by May 10, 1999.

Some Frequently Asked Questions (FAQs) Concerning NELAC QS (Chapter 5):

1. Question: If a mandated method (required by EPA or State Authority) is less stringent than the QS standards what do I follow?

Answer: The most restrictive/demanding.

2. Question: Do the QS standards require the use of any specific method?

Answer: No

3. Question: Do the QS standards allow for the use of the PBMS approach?

Answer: Yes. However, the QS standards may include additional QS checks/requirements (considered by NELAC to be essential) than those associated with a PBMS method for a given project. Such additional requirements would also apply to conventional or non-PBMS methods as well.

4. Question: Do the QS standards apply to small laboratories?

Answer: Yes. The standards include essential QC procedures and are applicable to environmental laboratories regardless of size and complexity. It is suggested that the amount of effort that will be required to attain the standards will be dependent on whether the laboratory already is operating under a quality system (with established and documented SOPs and QC procedures) more than upon the size of the laboratory.

5. Question: If my laboratory is measuring high level concentrations and is set-up (perhaps even optimized) to analyze at such levels and is only interested in whether a high level regulatory limit is exceeded, why do I have to determine a detection limit?

Answer: A detection limit is considered essential to verify (confirm and document) that the laboratory is actually able to detect and measure at the regulatory or decision limit. Detection limit determinations are also considered an important consideration with regard to the quantitation range selection and particularly with regard to the choice of the concentration of the lowest calibration standard. Changes to the standard will be proposed at the January 1999 Interim Meeting, which no longer specify that the MDL (40 CFR Part 136) procedure be employed, unless it is mandated by the test method or applicable regulation. In the proposed revision, the term “detection limit” may not be the lowest concentration level attainable by a given analytical method, but rather that it is a concentration that is actually measurable (and verified) using the procedures, e.g., equipment, analytical method, routinely employed for sample analyses (could be relatively high concentration). The detection level should be appropriate or relevant for the intended use of the data. In some cases this will of necessity be the lowest concentration level attainable, e.g., low level drinking water or wastewater permit limits.

6. Question: Why are we revisiting the calibration and detection parts of the

standards?

Answer: At NELAC IV the Quality Systems Committee received numerous comments that the calibration and detection parts of the standards were too prescriptive and were not consistent with a PBMS environment. The Committee has attempted to propose changes to the calibration and
detection parts of the standards that provide essential elements for those two quality system standards and that will support the anticipated needs of PBMS. The Committee believes the proposed language is less prescriptive (i.e., more flexibility), yet hopefully still ensures the quality of the analytical data.

In making these proposed changes the Committee has attempted to balance the need for more flexibility in the standards with the desire to not go to far and introduce excessive flexibility that could prove to be too vague or ill-advised. The Committee is currently discussing and considering its proposed language and public comments on the proposed language changes. The Committee is committed to assuring that the NELAC Quality Systems standards provide a foundation for PBMS implementation.

7. Question: Several States have indicated that it is very desirable that a laboratory already be actively analyzing samples for a particular program and by a method for which they want to be accredited. However, these same states have relayed that this ideal scenario is often not the case, as a laboratory may request accreditation in attempts to expand their scope of analytical services or in order to satisfy contractual requirements. These states ask: How will the QS standards help ensure that laboratories will have sufficient data for an onsite assessment especially given the proposed changes to the MDL section?

Answer: The MDL, section D.1.4, in the 1998 NELAC standards has a requirement that "MDLs" be determined initially (40 CFR Part 136, Appendix B) and be verified yearly by the analysis of at least one clean matrix sample spiked at the current reported MDL. Under the proposed revision to Section D.1.4, "Detection Limits" are to be determined initially and each time there is significant change in the test method or instrument type. The proposed standard still requires "MDL" if required in the mandated test method or applicable regulation. If the MDL is not required a "detection limit" must still be determined. Therefore the new section D.1.4 requirements should still help assure that performance data will be available for review by inspectors . In addition, laboratories are required to successfully complete two out of three proficiency testing (PT) samples yearly and this data would be available for review, as per section 5.5.4 and Chapter 2) . However, under the current PT requirements this may only include one method of multiple methods employed by a laboratory for a given parameter group, e.g., metals.

Laboratories also must perform an IDOC (5.10.2.1, D.1.3 Method Evaluation and Appendix C) . This data would be available for on-site review. Also note that the QS committee plans to expand Appendix C (IDC) procedures prior to NELAC V to make it applicable to methods for which spiking is difficult or impossible, e.g., Total Suspended Solids, which should further ensure that performance data is available for review.

In addition, under Section 5.6.2.3.c. of QS, the Laboratory Management must ensure that the training of personnel is kept up-to-date, which includes a analyst certification to perform the most recent version of the test method (the approved method or standard operating procedure) and documentation of continued proficiency by at least one of the following once per year:

i. acceptable performance of a blind sample (single blind to the analyst),

ii. another initial demonstration of method capability,

iii. successful analysis of a blind performance sample on a similar test method using the same technology,

iv. at least four consecutive laboratory control samples with acceptable levels of precision and accuracy, and

v. if i-iv cannot be performed, analysis of authentic samples that have been analyzed by another trained analyst with statistically indistinguishable.

These requirements should further help assure performance data is available on-site for review.

Attachment D

ACKNOWLEDGEMENT LETTER, REVIEW GUIDELINES, and COMMENTER TEMPLATE
Quality Systems Committee
March 16, 1999

Date:

Dear :

On behalf of the Quality Systems Committee, thank you for your comments on the Chapter 5 standards of the National Environmental Laboratory Accreditation Conference (NELAC). The standards are routinely reviewed and updated. Continual improvement of the standards is the focal point of NELAC process. We encourage your continued written input as well as your attendance at the NELAC interim meeting and yearly conference. Also, our committee routinely schedules 1-2 open forum meetings during each calender year.

Our committee requests that all comments be supplied in electronic format (WordPerfect if possible) and that handwritten, hardcopy and the use of color fonts be avoided. Comments are considered by the QS committee on a first come basis. We have placed a template (table) for comments on the NELAC Web page, which we hope will ensure that the processes is efficient. With this process we hope that emphasis can be placed on consideration of the comments so that the available time is not spent in the mechanics of exchanging information (US Mail and re-typing comments). Routinely, each set of comments is assigned a QS leader who will complete the comment table including suggested language for any proposed changes to the NELAC standards. The Leader will guide a discussion of the comments during routine committee meetings. The minutes of the meeting (posted on the web site) will capture the information in the completed table from committee discussions, thoughts/rationale and present the final decisions.

Again, thank you for taking the time and effort to improve the NELAC Quality System standards.

Sincerely,
Joseph Slayton, Chair
Quality Systems Committee

QS Approach: **Comments Received and QS Response:**

1. A form letter will be sent to each commentor notifying them of receipt of the comment and of the QS's approach to reviewing comments and associated updates to the standards.

2. QS will consider the comments in the order received.

3. A QS committee member will be designated as the lead on each set (or up-set) of the comments from each commentor, who will provide written comments and who will lead a discussion with the full committee on any proposed changes to the standards (including providing the proposed standard language).

4. Proposed changes to the standards will be captured in the QS meeting minutes which are posted on the NELAC Web page.

5. All comments and written responses will be attached to QS meeting minutes.

6. No colors to be used in the comments nor in the response. Use double underlines for additions and strike-outs for removal of items.

7. All comments are to be provided in WordPerfect or rich text format using the following the following table:

GUIDING PRINCIPLES/REVIEW CRITERIA

The QS Committee established a set of criteria by which to evaluate the requirements specified in Chapter 5. The standards in Chapter 5 should meet the criteria listed below:

Flexible:

Allow laboratories freedom to use their experience and expertise in performing their work and allow for new and novel analytical methods and approaches, (e.g., Performance Based Measurement System [PBMS]). That the standards specify the "What" and avoid were possible the "How To", (e.g., control limits must be developed to determine if a QC check result is acceptable, the standards do not specify how the laboratory is to determine these limits).

Auditable:

Sufficient detail is included so that the accrediting authorities evaluate laboratories consistently and uniformly.

Practical/Essential:

The standards are necessary QA policies and QC procedures and that these standards should not place an unreasonable burden upon laboratories.

Widely Applicable:

International scope- consistent with ISO Guide 25. Represent QA policies, which establish essential QC procedures, that are applicable to environmental laboratories regardless of size and complexity.

Appropriate For The Use of the Data:

Helps ensure that associated environmental data is of known quality and that the quality is adequate for the intended use of the data.

Comment ID #: , Source of Comments (Name): QS Lead on Response (Name):			
Standard Rev. # SECTION# and QS Standard Narrative (To Filled In by Commentor)	**COMMENTwith Rationale to QS (To Be Filled in my Commentor)** **New Wording for Standard (To Be Filled In by Commentor)**	**QS Leader Provided Proposed Change (Commentor Leave Blank)**	**RATIONAL (from QS Leader) (Commentor Leave Blank)**